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10/525,772

11/16/2005

Steven Wheeler

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EXAMINER

PATEL, NEHA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,772	Applicant(s) WHEELER, STEVEN	
	Examiner NEHA PATEL	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/11/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. This is first office action on the merits in response to the application filed on 02/28/2005.
2. Claims 1-15 are currently pending and have been examined.

Priority

3. This application claims priority of PCT/CA04/01817 files on 10/08/2004.
Applicant's claim for the benefit of this prior-filed application is acknowledged.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 04/11/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

5. Claim 9 is objected to because of the following informalities: Claim 9 recite phrase "the at least one workstation", It appears to the examiner that applicant meant to write "an at least one workstation" or "at least one workstation".
Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim element “means for modifying....” and “means for generating...” is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function.

For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

9. Regarding claim 9, the phrase "may be" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 9-12 and 15 rejected under 35 U.S.C. 102(e) as being anticipated by Hildebrand et al. (**US 6,470,320 B1**).

With respect to claim 9:

Hildebrand et al. teaches *a medical decision support system including a hospital information system including at least one user workstation, said system comprising:*

(a) at least one server comprising: a database comprising diagnosis and treatment rules; means for modifying the diagnosis and treatment rules in accordance with outcome information; a database comprising patient-specific information; and means for generating diagnostic or treatment options by comparing the patient-specific

information to the rules database; (By disclosing, Central computer system 14, See at least fig. 1 as well as associated text.)

(b) a second server, which may be the same as the at least one server, comprising a database of outcome events and outcome data, and means for generating pre-defined reports and ad-hoc reports; (By disclosing, Disease management logic module 40, See at least fig. 1 as well as associated text.)

(c) wherein the at least one workstation comprises: a data interface for collecting patient-specific information and transmitting it to the server; a user interface for receiving and displaying the diagnostic or treatment options; (By disclosing, local facility system 12, See at least fig. 1 as well as associated text.)

(d) and wherein a second workstation, which may be the same as the at least one workstation, comprises: an outcome interface for collecting outcome information and transmitting it to the second server; and a report interface for receiving and displaying reports received from the second server. (By disclosing, local facility system 12 where fourth patient information signals which useful to update database 46. See at least fig. 1 as well as associated text.)

With respect to claim 10:

Hildebrand et al. teaches limitations of claim 9. Hildebrand et al. further teaches *the data interface and user interface are provided by a first workstation and the outcome interface and report interface are provided by a second workstation. (By disclosing, The local facility system 12 is provided with a local computer 18 which is connected to a*

data input device 20, a digital input device 22 and an output device 24 as indicated by the signal paths 26, 28, and 30, respectively. See at least column 4, 5th paragraph.)

With respect to claim 11:

Hildebrand et al. teaches limitations of claims 9 and 10. Hildebrand et al. further teaches *the at least one server and the second server are separate servers*. (By disclosing, the hardware and software of the local facility systems 12, regional facility systems 16 and central facility systems 14 could be implemented as a single computer system or a **plurality of interconnected computer systems**. See at least column 4, 3rd paragraph.)

With respect to claim 12:

Hildebrand et al. teaches limitations of claims 9, 10 and 11. Hildebrand et al. further teaches *the at least one server and the at least one workstation are connected by a local area network, a wide area network, or the Internet*. (By disclosing, Examples of such communications systems include internal busses, local area networks, wide area networks, point-to-point shared and dedicated communications, infra-red links, microwave links, telephone links, CATV links, satellite and radio links and fiber-optic links. See at least column 3, 2nd paragraph.)

With respect to claim 15:

Hildebrand et al. teaches limitations of claim 9. Hildebrand et al. further *a plurality of user workstations in at least two different locations or institutions*. (By disclosing, Each of the local facility systems 12 can be located at a local treatment facility which is

positioned anywhere that is convenient or accessible for the selected patient, such as at the selected patient's home or in a health care provider's office where a selected patient presents to receive a check-up, examination, physical or the like. The central facility systems 14 are typically located in a central reading center which is disposed remotely from the local facility system 12 and it is envisioned that the central facility systems 14 will be located at or near an urban area or medical research institute where it is likely that medical specialists will reside. See at least column 3 and 4, last and first paragraph respectively.)

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
15. Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segal (**US 6,212,519 B1**) in view of Hildebrand et al. (**US 6,470,320 B1**).

With respect to claim 1:

Segal teaches *a computer-implemented method of supplying diagnostic or treatment information, or both, to a health professional, comprising the steps of:*

- *creating a database of diagnosis and treatment rules; (By disclosing, the invention provides a system that processes qualitative expressions to determine numerical values of probability, and employs these numerical values of probability to **build a database** of probability data that represents the likelihood that the presence of a particular finding occurs in a particular **disease or disorder**. See at least column 4, 1st paragraph.)*

- *collecting patient-specific information;* (By disclosing, The displays direct the medical professional **to identify those findings in a particular patient.**

Findings can include symptoms, patient histories, laboratory tests, environmental factors, the patient's demographic profile or any other information. See at least column 4, last paragraph.)

- *applying the diagnosis and treatment rules to the patient-specific information and determining suitable diagnostic or treatment information, or both;* (By disclosing, The program can employ the findings to suggest one or several possible diseases on the basis of the entered finding profile. See at least column 4, last paragraph.)

Segal does not specifically disclose following. However Hildebrand et al. teaches following;

- *collecting outcome information including actual treatment and patient response information; modifying the database of diagnosis and treatment rules in accordance with the outcome information.* (By disclosing, the database 46 is updated so that the experiences, treatment recommendations and progress of the selected patient can be used to provide predictive probabilities for other patients. See at least column 12, 2nd paragraph.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of supplying diagnostic or treatment information disclosed by Segal with technique of updating the database of diagnosis and treatment

rules in accordance with the outcome information disclosed by Hildebrand et al. so that predictive probabilities determined can become increasingly more accurate.

Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

With respect to claim 2:

Segal in view of Hildebrand et al. teaches limitations of claim 1. Segal further teaches *said diagnostic or treatment information is relevant to critical or non-critical adverse medical events*. (By disclosing, the system employs these numerical values of probability to build a database of probability data that can determine the likelihood that the presence or absence of a particular finding affects the likelihood of a patient having a particular **disease or disorder**. See at least column 3, under detailed description.)

With respect to claim 3:

Segal in view of Hildebrand et al. teaches limitations of claims 1 and 2. Segal further teaches *the patient-specific information comprises one, some or all of the following: age, weight, sex, medical history, recent medications, current or past surgical procedures, current vital signs, or current medical condition*. (By disclosing, the displays direct the medical professional to identify those findings in a particular patient. Findings can include symptoms, patient histories, laboratory tests, environmental factors, the patient's demographic profile or any other information. See at least column 4, last paragraph.)

With respect to claim 4:

Segal in view of Hildebrand et al. teaches limitations of claims 1 and 2. Segal does not specifically disclose *diagnosis and treatment rules include information specific to an institution in a particular geographical location*. However Hildebrand et al. teaches *diagnosis and treatment rules include information specific to an institution in a particular*

geographical location. (By disclosing, the digital disease management system 10 may have one central facility system 14 which is capable of recommending treatment for eye exams (diabetic retinopathy) and another central facility system 14 which is capable of recommending treatment for nervous systems See at least column 6, first paragraph.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of supplying diagnostic or treatment information disclosed by Segal in view of Hildebrand et al. with technique of including information specific to an institution in a particular geographical location disclosed by Hildebrand et al. so that patient information may be directed to particular institution based upon patient's treatment need and capabilities of institution. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

With respect to claim 8:

Segal in view of Hildebrand et al. teaches limitations of claim 1. Segal does not specifically disclose *the outcome information is collected from more than one institution or location.* However Hildebrand et al. teaches *the outcome information is collected from more than one institution or location.* (By disclosing, the system 10 is provided with a plurality of local facility systems 12, a plurality of central facility systems 14 and a plurality of regional facility systems 16. Only one of the local facility systems 12, the central facility systems 14 and the regional facility systems 16 are shown in FIG. 1 for purposes of clarity. See at least column 3, 6th paragraph.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of supplying diagnostic or treatment information disclosed by Segal in view of Hildebrand et al. with technique of collecting outcome information from more than one institution or location disclosed by Hildebrand et al. so that wide variety of outcome information used to update database of diagnosis and treatment for more accurate prediction of disease. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Segal (**US 6,212,519 B1**) in view of Hildebrand et al. (**US 6,470,320 B1**) and further in view of Gilbert et al. (**US 6,381,576 B1**).

With respect to claim 7:

Segal in view of Hildebrand et al.. teaches limitations of claim 1. Neither Segal nor Hildebrand et al. specifically disclose *the outcome information does not include information which could identify the patient, the institution or the health professional*. However Gilbert discloses *the outcome information does not include information which could identify the patient, the institution or the health professional*. (By disclosing, the diagnostic and treatment information data structure thus encapsulates, without identifying a specific patient, information regarding a particular diagnosis-treatment cycle for an individual patient. See at least column 2, Summary of the invention.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of supplying diagnostic or treatment information disclosed by Segal in view of Hildebrand et al. with technique of *having outcome information which does not include information which could identify the patient, the institution or the health professional* disclosed by Gilbert et al. so outcome information can be used to update diagnosis and treatment database without compromising with the patient's privacy. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

17. Claims 5 and 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Segal (**US 6,212,519 B1**) in view of Hildebrand et al. (**US 6,470,320 B1**) and further in view of Official Notice taken by examiner.

With respect to claim 5:

Segal in view of Hildebrand et al. teaches limitations of claims 1, 2 and 3. Segal does not specifically disclose *the suitable diagnostic information comprises at least two different diagnoses separately ranked in order of higher probability*. However Examiner takes official notice that it old and well known that *the suitable diagnostic information comprises at least two different diagnoses separately ranked in order of higher probability*. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of supplying diagnostic or treatment information disclosed by Segal in view of Hildebrand et al. with technique of having the suitable

diagnostic information comprises at least two different diagnoses separately ranked in order of higher probability to assist physician's decision making. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

With respect to claim 6:

Segal in view of Hildebrand et al. teaches limitations of claims 1, 2 and 3. Segal does not specifically disclose *the suitable treatment information comprises at least two different treatment alternatives separately ranked in order of higher likelihood of success*. However Examiner takes official notice that it old and well known that disclose *the suitable treatment information comprises at least two different treatment alternatives separately ranked in order of higher likelihood of success*. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of supplying diagnostic or treatment information disclosed by Segal in view of Hildebrand et al. with technique of having the suitable treatment information comprises at least two different treatment alternatives separately ranked in order of higher likelihood of success to assist physician's decision making. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

18. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hildebrand et al. **(US 6,470,320 B1)** in view of Official Notice taken by examiner.

With respect to claim 13 and 14:

Hildebrand et al. teaches limitations of claims 9 and 13. Hildebrand et al. does not *specifically disclose one or more of the data interface, user interface, outcome interface and report interface is a web browser and the user interface comprises a touch-sensitive screen*. However Examiner takes official notice that it old and well known to use data interface as web browser or touch sensitive screen. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine a *medical decision support system* disclosed by Hildebrand et al. with technique of having data interface as web browser or touch sensitive screen to these are easier and quicker means to input data into system. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Neha Patel** whose telephone number is **571.270.1492**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the

examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY, O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

/N. P./
Examiner, Art Unit 3686
August 14, 2009

/Gerald J. O'Connor/
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